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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,241	01/23/2004	Christopher A. Sikora	BJS-3929-5	4510

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EXAMINER	
GRASER, JENNIFER E	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,241	SIKORA ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-24* is/are pending in the application.

4a) Of the above claim(s) *7-24* is/are withdrawn from consideration.

5)☒ Claim(s) *1* is/are allowed.

6)☒ Claim(s) *3-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Acknowledgment and entry of the Amendment submitted on 1/12/07 is made. Claims 1 and 3-24 are currently pending. Claims 7-24 were previously withdrawn from consideration as being drawn to a non-elected invention.

Claims 1 and 3-6 are under examination.

Claim Rejections - 35 USC § 112-2nd paragraph

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is vague and indefinite because it recites the protein is "identified by immunological reaction with an antiserum or antibodies from antiserum obtained from an animal which has been first vaccinated with a component extracted from a first infectious agent..". It is clear how antibodies could be obtained from antiserum, but is unclear how antiserum is obtained from antiserum. The claim recites a "first infectious agent" and a "second infectious agent"; however, it is unclear what is encompassed by the "infectious agent". What are considered infectious agents? Are they bacterial, viral, etc.? Are the proteins, cells, polysaccharides, etc.? The metes and bounds of the claim language cannot be understood. While the specification can be used to provide

definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Claim 5 recites the limitation "wherein said mammal is a mouse or human". There is insufficient antecedent basis for this limitation in the claim because claim 1 no longer recites 'infected mammal'.

Claim 6 recites the limitation "infectious agent is a bacterium, virus, fungus, yeast or parasite, said first infectious agent being B.abortus and said second infectious agent being Francisella tularensis". There is insufficient antecedent basis for this limitation in the claim because claim 1 from which it depends does not recite any 'infectious agent'. Additionally, the claim is vague and indefinite because it recites that the infectious agent may be a bacterium, virus, fungus, yeast or parasite, but then recites that the first infectious agent is B.abortus and the said infectious agent is F.tularensis. These are both bacterium. Accordingly, it is unclear how the infectious agents could be a fungus, yeast or parasite when the claim effectively limits both the first and second infectious agents to bacteria. Accordingly, the claim is vague and confusing. Clarification and correction is requested.

Claim Rejections - 35 USC § 112-scope of enablement

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 3 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "an isolated subcellular protein having a molecular weight of about 52kDa, said protein having been expressed from a *Francisella tularensis* subculture growing in synthetic salts medium at pH 6.5' and 'wherein said subcellular protein is identified by immunological reaction with antibodies or antiserum obtained from an animal which has been first vaccinated with a Brucella abortus O-polysaccharide vaccine and then infected with multiple lethal doses of Francisella tularensis and survived the multiple lethal doses of F.tularensis due to the first vaccination with B.abortus O-polysaccaharide", does not reasonably provide enablement for "said subcellular protein, wherein said infected mammal is first vaccinated with *any* component extracted from a first infectious agent and then infected with a high dosage of a second infectious agent" as recited in instant claim 3 or wherein said infectious agent is any bacterium, virus, fungus, yeast, parasite or any infectious agent of B.abortus as recited in claim 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification teaches that it was known in the prior art that sera from individuals with infections of tularemia generally do not acquire immunity to the infecting bacteria and that the sera of those vaccinated or infected with F.tularensis has antibodies with affinity for low molecular weight proteins of

F.tularensis. These low molecular weight proteins did not appear to give protection when used as vaccines (Golovliov et al. Vaccine. 1995. 15(3): 261-267).

The prior art also taught that the capsule of F.tularensis was not a virulence factor. The prior art also taught that toxins were not present for F.tularensis. Applicants did find that there appeared to be a toxic agent expressed from F.tularensis which had a delayed action, e.g., 24 hours. Usually, toxins act immediately on host target cells because of their detergent or enzymatic activity. It was by cross-protecting mice against related bacterium, B.abortus, **using the O-polysaccharide vaccine which allowed cross-protection against high doses of F.tularemia which would normally kill the mice**. The surviving vaccinated mice had antibodies in their sera that recognized the latter bacterial components expressed during the disease process. These antibodies recognized previously overlooked proteins. Applicants identified a 52-kDa protein from this procedure that was specific for F.tularemia. Applicants demonstrated that this specific protein was secreted in synthetic salt medium of weak acidity and were not present when cells were disrupted by sonication to mimic lysis. This appears to signify growth stress, similar to what occurs during the course of normal infection when a bacterium is acquiring metabolites for growth. Tests performed by Applicants demonstrated that the 52kDa protein was toxic virulence factor of F.tularensis. Applicants state on page 37, lines 15-17, that time allowed them only to pursue the 52kDa protein.

The instant claims, 3 and 6, are broadly drawn to proteins using an isolation procedure which indluces vaccination with any bacterium, virus, parasite, yeast or fungus to produce the claimed 52kDa protein. The instant specification has only taught the isolation and characterization of the 52kDa protein from F.tularensis. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." In the instant case, the specification has only enabled the 52 kDa protein which was isolated by by cross-protecting mice against related bacterium, B.abortus, using the O-polysaccharide vaccine which allowed cross-protection against high doses of F.tularemia which would normally kill the mice. The surviving vaccinated mice had antibodies in their sera that recognized the latter bacterial components expressed during the disease process. These antibodies recognized previously overlooked proteins. Applicants identified a 52-kDa protein from this procedure that was specific for F.tularemia. Applicants demonstrated that this specific

protein was secreted in synthetic salt medium of weak acidity and were not present when cells were disrupted by sonication to mimic lysis. It would take undue experimentation on the part of the skilled artisan to use any other infectious agent whether it be viral, parasitic, fungal, bacterial or another B.abortus antigen in combination with any lethal second infectious agent from any virus, bacteria, parasite, yeast or fungus to cause production of the 52kDa F.tularensis protein. The specification fails to teach the use of any other infectious agents for the production of the 52kDa protein. It is unclear that the use of any infectious agent would cause the same protein to be expressed by F.tularenis. It would take undue experimentation for one of skill in the art to use any other infectious agents for the isolation of the claimed 52kDa protein.

Allowable Subject Matter

5. Claim 1 is allowed. Claim 4 is dependent on a rejected claim and would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

Jennifer Graser 3/28/07
Primary Examiner
Art Unit 1645